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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,127	11/19/2001	Tony Peled	00/21438	8221

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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# Office Action Summary

Application No.

09/988,127

Applicant(s)

PELED ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-100 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Applicants amendment filed 11/19/01 , Paper NO: 6 is acknowledge.

*Claims 37-100 are pending.*

### ***Restriction Requirement***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 37-43 drawn to a method of *in vivo* expanding a population of cells, while at the same time inhibiting differentiation of the cells, classified in Class 424, subclasses 93.7 and 577. 405.
  - II. Claims 37, 44- 53 drawn to a method of *ex-vivo* expanding a population of cells, while at the same time inhibiting differentiation of the cells wherein said cells are non-differentiated stem cells, classified in Class 435, subclasses 325, 375, 405.
  - III. Claims 37, 44- 53 drawn to a method of *ex-vivo* expanding a population of cells, while at the same time inhibiting differentiation of the cells, wherein said cells are committed progenitor cells, classified in Class 435, subclasses 325, 375, 405.
  - IV. Claims 54-57, drawn to a method of hematopoietic cell transplantation, wherein said cells are enriching for non-differentiated stem cells, classified in Class 424, subclasses 93.7 and 577.
  - V. Claims 54-56 and 58 , drawn to a method of hematopoietic cell transplantation, wherein said cells are enriching for committed progenitor cells , classified in Class 424, subclasses 93.7 and 577.
  - VI. Claims 59-60 , drawn to a method of genetically modifying stem cells, classified in Class 435, subclass 455.
  - VII. Claim 61, drawn to a method of adoptive immunotherapy, classified in Class 424, subclass 577.

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VIII. Claims 62-65, drawn to a method of mobilization of bone marrow stem cells into the peripheral blood, classified in Class 424, subclasses 184.1 and 577.

IX. Claims 66-67, drawn to a method of decelating maturation. differentiation of erythroid precursor cells, classified in Class 424, subclasses 184.1 and 577.

X. Claims 68-69, drawn to a therapeutical ex-vivo cultured cell preparation, classified in Class 435, subclasses 325 and 375.

XI. Claim 70, drawn to a method of preservation of stem cells, classified in Class 435, subclasses 325 , 375 and 405.

XII. Claim 71, drawn to a stem cell collection bags, separation and washing buffers, classified in Class 435, subclass 810.

XIII. Claim 72, drawn to an assay of determining whether a transitional metal chelator which binds copper causes inhibition or induction of differentiation of cells , wherein said cells are stem cells or cells of a substantially non-differentiated, comprising monitoring differentiation of said cells, classified in Class 435, subclasses 325 , 375 and 405.

XIV. Claim 72, drawn to an assay of determining whether a transitional metal chelator which binds copper causes inhibition or induction of differentiation of cells , wherein said cells are progenitor cells comprising monitoring differentiation of said cells , classified in Class 435, subclasses 325 , 375 and 405.

XV. Claim 73, drawn to an assay of determining whether a transitional metal chelator which binds copper causes inhibition or induction of differentiation of cells comprising monitoring copper content of said cells , classified in Class 435, subclasses 325 , 375 and 405.

XVI. Claims 74, 75, 77-88, drawn to a method of *in-vivo* inducing differentiation in a population of cells, wherein said cells are non-differentiated stem cells, classified in Class 424, subclasses 93.7 and 577.

XVII. Claims 74, 75, 77-88, drawn to a method of *in-vivo* inducing differentiation in a population of cells, wherein said cells are committed progenitor cells, classified in Class 424, subclasses 93.7 and 577.

XVIII. Claims 74, 76-88, drawn to a method of *ex-vivo* inducing differentiation in a population of cells, wherein said cells are non-differentiated stem cells classified in Class 435, subclasses 326 and 377.

XIX. Claims 74, 76-88, drawn to a method of *ex-vivo* inducing differentiation in a population of cells, wherein said cells are committed progenitor cells classified in Class 435, subclasses 326 and 377.

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XX. Claims 89-90, drawn to a method of inducing terminal differentiation in acute leukemic cells, wherein said cells are *in-vivo* cells, classified in Class 424, subclass 93.7.

XXI. Claims 89-90, drawn to a method of inducing terminal differentiation in acute leukemic cells, wherein said cells are *ex-vivo* cells, classified in Class 435, subclasses 326 and 377.

XXII. Claims 91-92, drawn to a method of inducing terminal differentiation of non- leukemic cells, wherein said cells are *in-vivo* cells, classified in Class 424, subclass 93.7.

XXIV. Claims 91-92, drawn to a method of inducing terminal differentiation of non- leukemic cells, wherein said cells are *ex-vivo* cells, classified in Class 435, subclasses 326 and 377.

XXV. Claim 93, drawn to a method of ex-vivo differentiation of normal stem cells into lineage committed progenitor cells, classified in Class 435, subclasses 326 and 377.

XXVI. Claim 94, drawn to a method of ex-vivo differentiation of stem cells into dendritic cell, classified in Class 435, subclasses 326 and 377.

XXVII. Claims 95 –100 drawn to a pharmaceutical composition for inducing differentiation in a population of cells, classified in Class 424 subclass 184.1 and 278.1.

3. Groups X and XXVII are different products. *Ex-vivo* cultured cell preparation and a pharmaceutical composition for inducing differentiation differ with respect to their structures, physiology and physicochemical properties; therefore each product is patentably distinct.

4. Groups I- IX and XI-XXVI are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups XXVII and XVII-XIX are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case transition metal chelator can be used in crystallography in addition to the methods of inducing differentiation.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject

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matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### Species Election

7. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I is elected, applicant is required to elect a specific method of *in vivo* expanding a population of cells, wherein a specific transition metal chelator is selected from the group recited in claim 43.

These species are distinct because specific method of *in vivo* expanding a population of cells, wherein a specific transition metal chelator is selected from the group recited in claim 43 differ with respect to the specific transition metal chelator; thus each specific method employing a specific transition metal chelator represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

B. If Groups II or III are elected, applicant is required to elect a specific method of *ex- vivo* expanding a population of cells, wherein : (i) a specific early acting cytokine is selected from the group recited in claim 47; (ii) a specific late acting cytokine is selected from the group recited in claim 49; (iii) a specific cells are derived from the sources recited in claims 50 and 51.

These species are distinct because a specific method of *ex- vivo* expanding a population of cells, wherein : (i) a specific early acting cytokine is selected from the group recited in claim 47; (ii) a specific late acting cytokine is selected from the group recited in claim 49; (iii) a specific cells are derived from the sources recited in claims 50 and 51 differ with respect to the specific a specific early acting cytokine, specific late acting cytokine and specific source of cells; thus each specific method employing a specific early acting cytokine, specific late acting cytokine and specific source of cells represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

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C. If Group V is elected, applicant is required to elect a specific method of hematopoietic cell transplantation, wherein a specific hematopoietic cells are selected from the source recited in claim 56.

These species are distinct because a specific method of hematopoietic cell transplantation, wherein a specific hematopoietic cells are selected from the source recited in claim 56 differ with respect to the specific source of hematopoietic cells; thus each specific method employing a specific source of hematopoietic cells represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature

D. If Group VIII is elected, applicant is required to elect a specific method of mobilization of bone marrow stem cells, wherein : (i) a specific cytokine is selected from the group recited in claim 64 and (ii) a specific agent is selected from the group recited in claim 65.

These species are distinct because a specific method of mobilization of bone marrow stem cells, wherein : (i) a specific cytokine is selected from the group recited in claim 64 and (ii) a specific agent is selected from the group recited in claim 65 differ with respect to the specific cytokine and specific agent; thus each specific method employing the specific cytokine and the specific agent represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature

E. If Group X is elected, applicant is required to elect a specific therapeutical ex-vivo cultured cell preparation, wherein a specific agent is selected from the group recited in claim 69.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

F. If one of Groups XVI- XIX is elected, Applicant is required to elect a specific method of inducing differentiation, wherein: (i) a specific cell is selected from the group recited in claim 78; (ii) one specific transition metal chelator is selected from the group recited in claims 80 or 82, or 84; (iii) a specific source of cells is selected from the group recited in claims 85 or 86.

These species are distinct because a specific method of inducing differentiation, wherein: (i) a specific cell is selected from the group recited in claim 78; (ii) one specific transition metal chelator is selected from the group recited in claims 80 or 82, or 84; (iii) a specific source of cells is selected from the group recited in claims 85 or 86 differ with respect to the specific cells, specific transition metal chelator and specific source of cells ; thus each specific method employing the specific cells, specific transition metal chelator and specific source of cells represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.



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G. If Group XXVII is elected, Applicant is required to elect a specific pharmaceutical composition for inducing differentiation in a population of cells, wherein a specific transition metal chelator is selected from the group recited in claims 97 or 99.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.


8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
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April 7, 2003

  
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